IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

HARRY KEEN, III, *Plaintiff*	:	**CIVIL ACTION**
v.	:	
C.R. BARD, INC., *et al.*, *Defendants*	:	**No. 13-5361**

MEMORANDUM

PRATTER, J. AUGUST 18, 2020

This products liability action concerns an inferior vena cava (IVC) filter, designed and manufactured by Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.,[1] which fractured after being implanted in Plaintiff Harry Keen, III's IVC.[2] Mr. Keen invokes Federal Rules of Evidence 402 and 403 in his two motions *in limine* which seek to preclude evidence concerning and/or references to (1) the Food and Drug Administration's (FDA) clearance of the G2 line of filters; (2) the FDA's lack of enforcement action against Bard; (3) FDA "approval" of Bard's IVC filters; (4) IVC filters' ability to save lives; and (5) statistics related to thrombi or pulmonary emboli in the general population. Except for prohibiting Bard from referring to devices which have only received FDA clearance as being "approved" by the FDA, the Court denies Mr. Keen's requests for the reasons detailed below.

BACKGROUND

Bard's entire product line of retrievable IVC filters has been the subject of a multidistrict litigation created in 2015 and presided over by Judge David Campbell of the District of Arizona.

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[1] This Memorandum references the defendants collectively as "Bard."

[2] "The IVC is a large vein that returns blood to the heart from the lower body." *In re Bard IVC Filters Prod. Liab. Litig.*, 289 F. Supp. 3d 1045, 1046 (D. Ariz. 2018).

See In re Bard IVC Filters Prod. Liab. Litig., MDL No. 15-2641 (D. Ariz.). This particular action was transferred to the multidistrict litigation in 2015 and returned to this Court in 2019.

Mr. Keen received a Bard G2X IVC filter, a prescription medical device placed in the largest vein leading to the heart in order to prevent blood clots. Approximately a year and three months after implantation, Mr. Keen's filter fractured, necessitating removal. Although a physician was unable to retrieve the fractured filter on the first attempt, all but two pieces of the filter which remain in a stable position were eventually retrieved. Mr. Keen brought this products liability action asserting the following claims: strict liability for design defect, manufacturing, and failure-to-warn; negligence based on design, manufacturing, and failure-to-warn theories; negligent misrepresentation; and breach of implied warranty of merchantability. He also seeks, in pertinent part, punitive damages. Mr. Keen's negligence and negligent misrepresentation claims survived summary judgment, and the Court reserved its determination as to whether he can seek punitive damages for a later date.

The FDA must approve or clear for market IVC filters and other medical devices. Although the FDA may approve a medical device shown to be safe and effective through the premarket approval process, 21 U.S.C. § 360e(a), a manufacturer can obtain "clearance" to market a device through the 510(k) process by showing that it is substantially equivalent to a device already on the market. Bard's G2X filter received FDA clearance through the 510(k) process.

LEGAL STANDARD

The relevance and admissibility of trial evidence is governed in part by the Federal Rules of Evidence 401, 402, and 403. Evidence is relevant pursuant to Rule 401 if it has any tendency to make a material fact more or less probable. FED. R. EVID. 401. Rule 402 provides that evidence is admissible unless otherwise excluded by the federal rules of evidence, a federal statute, the

Constitution, or other rules prescribed by the Supreme Court and that irrelevant evidence is inadmissible. FED. R. EVID. 402. Relevant evidence may otherwise be excluded under Rule 403 if its probative value is substantially outweighed by the danger of "unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." FED. R. EVID. 403. Evidentiary rulings on motions *in limine* are subject to a district court's discretion. *Abrams v. Lightolier, Inc.*, 50 F.3d 1204, 1213 (3d Cir. 1995) (citations omitted).

DISCUSSION

The Court discusses both of Mr. Keen's motions *in limine* in turn.

I. Mr. Keen's Motion *in Limine* to Preclude References to the Clearance of Bard IVC Filters by the FDA, Lack of Enforcement Action as Proof of Safety and Efficacy, and Refrring [sic] to the Bard IVC Filters as "Approved" by the FDA

Citing Rules 402 and 403, Mr. Keen moves to preclude references to the FDA's clearance of Bard's IVC filters, references to the FDA's lack of enforcement action against Bard, and referring to Bard IVC filters as being "approved" by the FDA.

A. FDA Clearance of G2 Line of Filters and Lack of Enforcement Action

As Judge Campbell similarly determined when assessing a nearly identical motion *in limine* concerning Georgia law, *In re Bard IVC Filters Prod. Liab. Litig.*, 289 F. Supp. 3d 1045, 1047 (D. Ariz. 2018), evidence of Bard's compliance with FDA regulations and the FDA's clearance of the G2 line of filters, while not dispositive, is relevant to the claims Mr. Keen brings under Pennsylvania law, as well as the punitive damages[3] he seeks, *see, e.g.*, *Birt v. Firstenergy Corp.*, 891 A.2d 1281, 1290 (Pa. Super. Ct. 2006) ("[E]vidence of industry standards and

[3] As Judge Campbell determined when assessing a similar standard under Georgia law, "[c]ompliance with federal regulations is not sufficient to preclude an award of punitive damages, but it is probative of whether the manufacturer acted with conscious indifference to the dangers posed by its device." *In re Bard*, 289 F. Supp. 3d at 1047.

regulations is generally relevant and admissible on the issue of negligence."); *Nigro v. Remington Arms Co., Inc.*, 637 A.2d 983, 990 (Pa. Super. 1993), *abrogated on other grounds by Aldridge v. Edmunds*, 750 A.2d 292 (Pa. 2000) ("Compliance with industry standards and custom weighs against Plaintiffs' argument of a culpable state of mind to underpin a demand for punitive damages, and further negates an inference of wanton indifference to the rights of others.").[4]

Mr. Keen attempts to paint the 510(k) clearance process as irrelevant because it is a comparative, rather than definitive, finding by the FDA that a device is safe and effective. Such an argument fails. The "[Safe Medical Devices Act of 1990] did introduce safety and effectiveness considerations into 510(k) review," even if the standard for those considerations is only comparative. *In re Bard IVC Filters Prod. Liab. Litig.*, No. 15-2641, 2017 WL 5625547, at *7 (D. Ariz. Nov. 22, 2017). A factfinder, after taking into consideration the history of the FDA's 510(k) clearance of the G2 line of filters, could determine that Bard took reasonable and appropriate steps in its effort to bring the G2X filter to market. Therefore, the Court follows Judge Campbell's lead in finding references to the 510(k) process to have probative value in this action. *See In re Bard*, 289 F. Supp. 3d at 1048 (citation omitted).

Mr. Keen's reliance on *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), is equally meritless. Mr. Keen cites *Lohr* for the proposition that the 510(k) process focuses on device equivalence rather than device safety. Pl.'s Mot. *in Limine* at 2-4[5] (Doc. No. 61) (quoting *Lohr*, 518 U.S. at 493). In *Lohr*, the Supreme Court inquired into whether FDA's clearance of a 510(k) device

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[4] To the extent Mr. Keen suggests that the jury is only to consider compliance evidence and regulations related to "safety," the Court rejects such a proposition. Judge Campbell rejected a similar argument when assessing a Georgia rule. *See In re Bard*, 289 F. Supp. 3d at 1048.

[5] Mr. Keen did not number the pages of his memorandum in support of this motion *in limine*. Accordingly, the Court follows the pagination set forth on the Court's Case Management/Electronic Case Files system.

preempted state law product liability claims under 21 U.S.C. § 360k(a). *See In re Bard*, 2017 WL 5625547, at *5. The *Lohr* decision did not, however, address whether evidence concerning FDA 510(k) clearance is admissible or relevant to the reasonableness of a manufacturer's conduct. As Judge Campbell determined, the fact that the 510(k) process focuses on device equivalence "does not render evidence of the 510(k) process irrelevant to the reasonableness of Bard's conduct." *In re Bard*, 289 F. Supp. 3d at 1047-48.

Mr. Keen's request for the Court to exclude any references to the FDA's lack of enforcement action regarding the G2 line of filters similarly fails. The fact that the FDA did not bring an enforcement action against Bard for its products during the nearly five years that the G2 line of filters was on the market before the G2X filter was implanted in Mr. Keen could be relevant to whether it was reasonable for Bard to design and manufacture the G2 line of filters and to continue marketing the G2X filter in 2010.

Mr. Keen's concerns raised under Rule 403 "can be adequately addressed without excluding relevant evidence to the detriment of Defendants." *See id.* at 1048-49. As Judge Campbell similarly determined, "[m]any of the relevant facts in this case occurred in the context of FDA 510(k) review, and much of the evidence is best understood in that context." *Id.* at 1049. In fact, "[a]ttempting to remove any references to the FDA from the trial would risk creating a misleading, incomplete, and confusing picture for the jury." *Id.* Bard may also be prejudiced if it is not permitted an opportunity to present to the jury a full picture concerning its decisions to market the G2 line of filters in 2005, and to continue marketing it through June 2010. During this time period, Bard was in frequent communication with the FDA regarding the performance of the G2 line of filters, Bard was performing a clinical trial on the G2 filter (at the FDA's request), and the FDA cleared Bard's G2 line of filters six times.

Finally, the Court, like Judge Campbell, is "convinced that efficient management of the evidence and adherence to the Court's time limits will avoid any risk of unnecessary or time-consuming mini-trials." *Id.*

Therefore, the Court denies Mr. Keen's request to preclude evidence of the FDA's clearance of the G2 line of filters and its lack of enforcement action brought against Bard.

B. Referring to Bard IVC Filters as Being "Approved" by the FDA

Mr. Keen fears that a reference to FDA "approval" concerning devices which only acquired FDA "clearance" would be highly misleading and confusing to the jury. Bard represented that it will not refer to the G2X filter as being "approved" by the FDA at trial. Following Judge Campbell's lead, this Court will not permit Bard to present evidence or argument that the FDA "approved" a filter which only acquired FDA "clearance." *Id.* ("Defendants will not . . . be permitted to present evidence or argument that the FDA 'approved' the G2 filter for market . . . ."). As explained by the pertinent FDA regulation: "Any representation that creates an impression of official approval of a device because of complying with the [510(k)] premarket notification regulations is misleading[.]" 21 C.F.R. § 807.97. The Court further notes that "any potential confusion can be cured, if necessary, by a limiting instruction regarding the nature of the 510(k) process." *Id.* (citation omitted). The Court therefore grants Mr. Keen's motion only as to this narrow request.

II. Mr. Keen's Motion *in Limine* No. 2 to Exclude any Reference to IVC Filters as Lifesaving Devices or to Statistics of Thrombi and Pulmonary Emboli

Mr. Keen moves to exclude any testimony or evidence alluding to or suggesting that IVC filters save lives or provide a clinical benefit under Rules 402 and 403. He also seeks to exclude statistics of thrombi and pulmonary emboli.

A. Reference to Bard's IVC Filters as Lifesaving Devices or Providing a Clinical Benefit

Mr. Keen contends that "[t]here is absolutely no evidence whatsoever" that supports the position that Bard's IVC filters save lives or offer a form of clinical benefit. Pl.'s Mot. *in Limine* at 3 (Doc. No. 62). In doing so, Mr. Keen cites a variety of testimony and medical literature which he contends demonstrates that Bard filters are not lifesaving or do not offer any clinical benefit.[6] Mr. Keen can certainly use his evidence to support his position at trial, but Bard will be permitted to do the same. Evidence is not irrelevant and unduly prejudicial merely because it conflicts with one party's side of the story.

Bard offers testimonial evidence demonstrating how the IVC filters "catch" and prevent large blood clots from traveling up the IVC to the heart or lungs and causing pulmonary embolus, a well-recognized and leading cause of sudden death. Because of IVC filters' ability to catch blood clots, Mr. Keen's implanting doctor and experts have testified that IVC filters may be lifesaving. *See, e.g.*, Sacks, Dep. Tr. at 22:12-15, Ex. C (Doc. No. 70-3) (testifying that because some patients can die from pulmonary embolism, IVC filters "may be life saving"); Kinney Dep. Tr. at 111:11-112:2, Ex. D (Doc. No. 70-4) (stating that because IVC filters prevent deadly pulmonary embolism, the devices are "viewed as potentially lifesaving medical devices"). Bard also offers medical literature supporting its position that IVC filters can save lives. *See, e.g.*, DeYoung, *Inferior Vena Cava Filters: Guidelines, Best Practice, and Expanding Indications*, 22 Seminars in Interventional Radiology 65, 68 (2016) (Doc. No. 70-8) (discussing a meta-analysis which found "an association between IVC filter placement and lower rates of symptomatic and fatal [pulmonary embolism] in the trauma patient population"); Carlin, *Prophylactic and Therapeutic Inferior Vena Cava Filters to Prevent Pulmonary Emboli in Trauma Patients*, 137 Archives of Surgery 521, 521

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[6] Bard disputes that the evidence cited by Mr. Keen truly supports such a proposition.

(2002) (Doc. No. 70-7) (finding that prophylactic use of an IVC filter in trauma patients reduced mortality from 11% to 3%, and that none of the patients who received a prophylactic IVC filter experienced a pulmonary embolism). This testimony demonstrates that Mr. Keen's contention that there is a dearth of evidence suggesting that Bard's IVC filters save lives or offer a clinical benefit is simply incorrect. Mr. Keen's challenges to Bard's evidence would be more appropriately addressed through vigorous cross examination, not exclusion.

Bard contends that the G2X filter's ability to save lives is relevant in that it provides the jury with the necessary context about the nature of the product. The Court agrees. Without understanding both the risks and benefits of the filter, the jury would be left without the proper context to understand why Bard would ever design or manufacture IVC filters or why Dr. Sacks implanted the G2X filter in Mr. Keen. The purpose of Bard's IVC filters and their medical benefits are also relevant to the inquiry of whether Bard violated its duty of care when designing the G2X filter. In the event Mr. Keen presents evidence that Bard knew that the G2X filter apparently offered no clinical benefit to patients and that it is not a lifesaving device—in support of his negligent failure-to-warn and punitive damages claims—Bard ought to have an opportunity to present evidence that the G2X filter can prevent blood clots from reaching a patient's heart or lungs.

Therefore, the Court denies Mr. Keen's request to exclude references to IVC filters as being able to save lives or provide a clinical benefit.

B. Statistics Related to Thrombi or Pulmonary Emboli in the General Population

Mr. Keen broadly asserts that statistics related to thrombi or pulmonary emboli in the general population have no probative value, and even if they did, the probative value is outweighed by the danger of unfair prejudice. But statistics related to thrombi or pulmonary emboli could

provide background information for the jury as to the context of Bard's IVC filters. Mr. Keen does not in any way explain why this evidence would unduly prejudice him, and the Court will not make such an argument on his behalf. Accordingly, the Court rejects this argument.

CONCLUSION

For the foregoing reasons, the Court grants in part and denies in part Mr. Keen's motion *in limine* concerning the FDA's clearance of Bard's IVC filters and the FDA's lack of enforcement actions against Bard. The Court narrowly grants this motion *in limine* only as it relates to precluding Bard from referring to products that did not go through the FDA's approval process as being FDA "approved." The remainder of the motion is denied. The Court also denies Mr. Keen's motion *in limine* to exclude references to IVC filters as lifesaving devices and to exclude statistics concerning thrombi and pulmonary elmboli. An appropriate order follows.

BY THE COURT:

GENE E.K. PRATTER
UNITED STATES DISTRICT JUDGE